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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/25/2006 has been entered.

Applicant's amendment filed on 04/25/2006 wherein claims 1, 17, 18, 26, 47, 49, 50, 56-57, 77, 158-163 have been amended, and claims 16, 45, 55, 75, 84, 150-151, and 153 have been canceled.

Applicant's amendment by reciting "human papilloma virus" instead of the abbreviated term "HPV" is sufficient to overcome the rejection of claims 57-60, 72, 75-85, 150-151, 153, 158-163 under 35 U.S.C 112, 2nd paragraph.

Claims 1-4, 13, 17-29, 35, 42, 46-54, 56-60, 65, 72, 76-83, 85, 158-163 are pending, and examined herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 17-24, 26-29, 35, 42, 46-53, 56, 158-163 are rejected under 35 U.S.C. 102(b) as being anticipated by Pusineri et al (US 6,559,199, PTO-892 of record).

Pusinari et al. discloses a composition comprising a silicone polymer and a antimicrobial agent, chlorinated isocyanurate being entrapped in or by silicone polymer for destroying microbes. Biocidal agents such as N-chloro derivatives of cyanuric acids, trichloroisocyanuric acid, sodium dichloroisocyanuric dihydrate are disclosed. See abstract; column 11, lines 44-46. The silicone polymers used have properties such as fluidity, film forming ability, paste type rheologies etc. See abstract; column 1, lines 5-10, lines 35-42, lines 63-65. The composition comprises polyorganosiloxane composition which can be crosslinked or which is in the form of a crosslinked elastomer, and a biocidal agent. The biocidal agents used are compounds which in the presence of water produce hypochlorous acid with high bactericidal capacity. See column 4, lines 10-17; column 11, lines 54-64. The biocides used have destructive properties towards bacteria, viruses, fungi, yeast etc. See column 4, lines 34-37. It is also disclosed that the active substance such as biocide is incorporated inside the silicone matrix by homogenization. The composition can also comprise additives such as fillers, silicas, aluminas, sweeteners, saccharides etc. See column 12, lines 33-37, lines 49-54. The process for preparing the composition is also disclosed. The compositions can be crosslinked at room temperature i.e is room temperature vulcanization or by heat. See column 13-16; column 22, claim 6. It is also disclosed that the compositions are compatible for contact with the skin and mucous membrane. See column 3, lines 24-28.

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A composition comprising 20 parts by weight of bactericide is also disclosed. See column 14, line 51. It is also taught that the combination of polyorganosiloxane and the biocidal agent leads to a system having a stably antiseptic over time. See column 4, lines 21-24, lines 38-51.

The recitation of the intended use of the claimed invention such as “for treating skin or mucosal membrane ailment caused by human papilloma virus” is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

It is well settled that “intended use” of a composition or product, e.g., “for treating skin or mucosal membrane ailment caused by human papilloma virus”, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same compounds, cross-linked silicone polymer, and chlorinated isocyanurate in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The recitation “said cross-linked polymer releasing said chlorinated isocyanurate upon hydration and/or diffusion” are deemed inherent properties, and must be possessed by the anticipatory composition so long as the composition of the prior art comprises cross-linked silicone polymer, and chlorinated isocyanurate.

Thus, Pusinari anticipates instant claims 1-4, 13, 17-24, 26-29 35, 42, 46-53, 56, 158-163.

Response to Applicant's arguments:

Applicant argues that “contrary to the teachings of Pusineri et al., the polymer utilized in the composition according to the present invention is already a cross-linked silicone polymer and is not designed so as to be cross-linked upon its application, as is the composition taught by Pusineri et al.” This argument has been considered, but not found persuasive because contrary to Applicant's assertion, Pusineri discloses a silicone elastomer system which comprises polyorganosiloxane which can be crosslinked or which is crosslinked in elastomer form, and a biocidal agent, N-chlorinated compound, and thus reads on instant claims. See column 4, lines 10-18 of Pusineri et al.

Applicant argues that “the concentration of the biocidal agent utilized in the composition taught by Pusineri et al. is relatively low, being lower than 1 weight percent, preferably lower than 0.8 weight percent...The small amounts of biocidal agent used in practice by Pusineri et al. clearly stand in line with the preventive purposes of the biocidal agent and demonstrate that the biocidal agent is not aimed at exerting a therapeutic activity at infected areas.” This argument has been considered, but not found persuasive because it is not commensurate in scope with the instant claims which are drawn to composition comprising a cross-linked silicone polymer and therapeutically effective amount of chlorinated isocyanurate, and not the intended use of said composition. Furthermore, Pusineri et al discloses a silicone elastomer system which comprises polyorganosiloxane which can be crosslinked or which is crosslinked in elastomer form, and a biocidal agent, N-chlorinated compound effective to destroy bacteria, viruses etc., and thus meet the instant claims.

Applicant argues that "Pusineri et al. fail to teach a process of preparing a composition, in which cross-linking of a silicone polymer is effected ex-vivo, before applying the composition". This argument has been considered, but not found persuasive because it is not commensurate with the instant claims which are directed to the method of preparing a composition, and not to whether the process i.e cross-linking is effected ex-vivo.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 54, 57-60, 65, 72, 76-83, 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pusineri et al (US 6,559,199, PTO-892 of record) as applied to claims 1-4, 13, 17-24, 26-29 35, 42, 46-53, 56, 158-163 above, in view of Bosch (US 6,017,515, PTO-892 of record).

Pusineri as discussed above teaches compositions comprising biocides, chlorinated isocyanurates in a cross-linked silicone polymer. Additionally, Pusineri also teaches that the biocidal silicone elastomer, in particular of room temperature vulcanization is simple to obtain, is inexpensive, safe and compatible for contact with skin, is effective from the point of antiseptic activity, and possesses excellent physical

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and chemical properties. See column 3, lines 24-29, lines 52-56. Pusineri also teaches that such biocidal silicone compositions containing N-chlorinated compounds in the presence of water produce hypochlorous acid or salts of this acid such as NaOCl, which have high bactericidal activity. It is further taught that the biocides used have destructive properties towards bacteria, viruses, fungi, yeast etc. See column 4, lines 34-37.

Pusineri et al. does not specifically teach the concentration of chlorinated isocyanurate in the range between 10 weight % and 90 weight % of the total composition, as in instant claims 25, and 54.

Pusineri does not specifically teach a method of treating skin ailment caused by human papilloma virus using a composition comprising chlorinated isocyanurate.

Bosch et al. (US 6,017,515) teaches a method of treating skin disorders and mucous membrane ailments caused by human papilloma viruses, such as for example warts comprising applying to the skin a composition comprising sodium hypochlorite, which is known to have bactericidal activity. See abstract; column 6, lines 40-46.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine the concentration of chlorinated isocyanurate employed in the composition of Pusineri et al, to obtain a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the concentration of chlorinated isocyanurate employed in the compositions, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in cosmetic science, involving merely routine skill in the art.

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It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect.

See *In re Boesch*, 205 USPQ

It would have been obvious to a person of ordinary skill in the art at the time of invention to use the biocidal composition comprising chlorinated isocyanurate in a cross-linked silicone polymer taught by Pusineri for the treatment of skin ailments caused by virus such as warts. One of ordinary skill in the art at the time of invention would have been motivated to use the composition taught by Pusineri for the treatment of warts because Pusineri teaches that the oxidizing agents, chlorine releasing compounds such as chlorinated isocyanurates are useful for treating diseases caused by viruses, fungi, bacteria etc., generally, and Bosch teaches that the chlorine releasing oxidizing agent, sodium hypochlorite is used in the treatment of warts caused by human papilloma virus. Thus one of ordinary skill in the art would have been motivated to use the biocidal silicone composition taught by Pusineri for skin ailment such as warts because the biocidal silicone composition taught by Pusineri on contact with water produces hypochlorous acid or salts of this acid such as NaOCl, which are used in the treatment of warts.

Therefore, claims 25, 54, 57-60, 65, 72, 76-83, 85 are seen to be clearly obvious over the cited prior art.

Response to Applicant's Arguments:

Applicant argues that "in sharp contrast to the teachings of Bosch et al., the composition taught by present invention is designed so as to slowly release the active

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ingredient from a polymer carrier that is selected capable of serving as a sustained release carrier and further enables continuous application thereof on the treated area.”

This argument has been considered, but not found persuasive. It is respectfully pointed out that Applicant is arguing against a single reference when the rejection was based on combination of references.

Applicant argues that “ The whole concept of treating ailments such as warts caused by HPV by slow-releasing an oxidizing agent entrapped within a polymer carrier, is neither taught nor suggested in Bosch et al. or Pusineri et al.”. This argument has been considered, but not found persuasive because Pusineri et al. discloses a silicone elastomer system which comprises polyorganosiloxane which can be crosslinked or which is crosslinked in elastomer form, and a biocidal agent, N-chlorinated compound effective to destroy bacteria, viruses etc., and thus crosslinked polyorganosiloxane in elastomer form inherently serves as a sustained release carrier of an active ingredient. Bosch teaches that the chlorine releasing oxidizing agent, sodium hypochlorite is used in the treatment of warts caused by human papilloma virus. Thus one of ordinary skill in the art would have been motivated to use the biocidal silicone composition taught by Pusineri for skin ailment such as warts because the biocidal silicone composition taught by Pusineri on contact with water produces hypochlorous acid or salts of this acid such as NaOCl, which are used in the treatment of warts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-60, 65, 72, and 76-83, 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (US 6,592,890, PTO-892 of record), and further in view of Boddie et al. (J. Dairy Sci. 79, 1996, 1683-1688, PTO-1449 of record) and Bosch (US 6,017,515, PTO-892).

Green discloses a wound dressing composition having an anti-infective activity for treating skin ailments caused by microorganisms such as bacteria, comprising a sheet comprising a crosslinked polymer matrix, and oxidant generating formulation within or on the polymer matrix. Green also discloses that the oxidant generating formulation is stable at least until contacted by a substrate, such as glucose, which is permeable into the polymeric matrix from the patient's body fluid. See column 4, lines 38-54; column 20, TABLE 3. It is also disclosed that the wound dressing can be a single sheet having the oxidant generating formulation, or plurality of stacked sheets, having the same composition. See column 4, lines 56-65. The conformable, flexible, and spreadable polymers such as cross-linked polymers of polyacrylamide, polyurea, polyurethane, polyvinylchloride, polyesters, polymethyl methacrylate, polytetrafluoroethylene, elastomeric organosilicon polymers etc., and combination thereof

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are disclosed. Hydrophobic polymers (elastomers) include such as medical grade Low Consistency Silicone elastomers such as NuSil MED-815, High consistency Silicone Elastomers suitable for extrusion such as NuSil MED-4550, as well as thermoplastic and room temperature vulcanization (RTV) silicone polymers. See column 11, lines 43-61.

Suitable anti-infective oxidizing agents disclosed are elemental iodine, hydrogen peroxide, hypohalites, hypothiocyanite etc. See column 14, lines 61-66. It is also disclosed that oxidizing agents hypohalites such as hypochlorites is formed upon wetting of the polymer in a body fluid. See column 15, lines 60-65. A 4 % by weight of oxidizing agent iodate in the composition is also disclosed. See column 21, lines 45-47. The data for anti-bacterial activity of oxidizing agent iodate in combination with iodide encapsulated Silicone patches is shown in column 19, TABLE 2. It is also disclosed that using a bilayer technique formulations of iodide and oxidizing agents of iodide can be encapsulated in a thin polymer comprising the upper layer, and this allows the sustained release of iodide and the oxidizing agent over extended period of time. See column 10, lines 8-15. Thus, the oxidizing agent is entrapped in the silicone polymer. It is further disclosed that the sponge like hydrogel composition containing oxidizing agent encapsulated in polymer can be fabricated into various shapes such as rolls, sheets etc. See column 12, lines 60-66. Disc shaped silicone devices containing the oxidizing agents in combination with NaCl were also prepared. See column 19, lines 20-23.

Green further teaches a method of preparing a pharmaceutical composition. Green teaches that finely ground oxidizing agent iodate and iodide were mixed into silicone

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elastomer and then the polymer was allowed to cure with dibutyl tin dilaurate catalyst. See column 17, EXAMPLE 1; column 19, lines 20-25; and column 21, EXAMPLE 3. A bilayer technique is also disclosed wherein the formulations of iodide and iodate, or other oxidizing agents of iodide are encapsulated in a thin polymer of polyurethane or silicone comprising the upper layer, and combined with another film of polyurethane or silicone containing polymer. See column 10, lines 7-24.

Green does not teach the particular oxidizing agent, chlorinated isocyanurate entrapped in the silicone polymer.

Green does not teach a method of treating skin ailment caused by human papilloma virus using chlorinated isocyanurate entrapped in the silicone polymer.

Boddie et al. disclose the use of oxidizing agent comprising a chlorinated isocyanurate in a similar formulation and a method of treating teat skin infected by microorganisms using said formulation. Boddie teaches that teat dip formulations containing an oxidizing agent hypochlorous acid (a source of free chlorine), liberated from sodium dichloroisocyanurate in water by hydrolysis, were effective against bacteria such as *Staphylococcus aureus* and *Streptococcus agalactiae* IMI. See page 1683, column 2, lines 24-29. Bodie further teaches that sodium dichloroisocyanurate has a greater biocidal activity than sodium hypochlorite. See page 1686, left hand column bottom paragraph-right hand column, line 19.

Bosch et al. (US 6,017,515) teaches a method of treating skin disorders and mucous membrane ailments caused by viruses, such as for example warts comprising

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applying to the skin a composition comprising sodium hypochlorite. See abstract; column 6, lines 40-46.

It would have been obvious to a person of ordinary skill in the art at the time of invention to substitute oxidizing agent taught by Green by another oxidizing agent, chlorinated isocyanurate in the wound dressing composition of Green for treating skin ailment because Boddie teaches teat dip formulation containing sodium isocyanurate for treating teat skin infections caused by bacteria.

It would have been obvious to a person of ordinary skill in the art at the time of invention to use a composition comprising oxidizing agent, chlorinated isocyanurate in a silicone polymer for the treatment of skin ailments caused by virus such as warts. because Bosch teaches that a oxidizing agent, sodium hypochlorite is used in the treatment of warts. One of ordinary skill in the art would have been motivated to use an oxidizing agent such as chlorinated isocyanurate with the expectation of obtaining a composition for the treatment of warts because (i) chlorinated isocyanurate on contact with water produces hypochlorous acid, and hypochlorous acid is more potent germicide than sodium hypochlorite for treatment of microbial diseases.

One of ordinary skill in the art would have been motivated to employ oxidizing agent, sodium isocyanurate entrapped in the polymer with the reasonable success of obtaining a sustained-release pharmaceutical composition for the treatment of skin ailment caused by human papilloma virus because Green teaches similar sustained-release composition for the treatment of skin ailments.

Therefore, claims 57-60, 65, 72, 76-83, and 85 are seen to be clearly obvious over the cited prior art.

Response to Applicant's Arguments:

Applicant's arguments that "although Green et al. describe compositions that are designed to slowly release an oxidizing agent, although Boddie et al. and Bosch et al. teach compositions for treating warts using chlorinated isocyanurate as a therapeutically active oxidizing agent for treating warts, none of the references teaches the use of a composition that is designed to slowly release the oxidizing agent upon hydration and/or diffusion for treating warts caused by HPV." This argument has been considered, but not found persuasive because 1) as elaborated by the applicant Green et al. describe compositions that are designed to slowly release an oxidizing agent, and also teach that the oxidizing agents therein hypohalites such as hypochlorites is formed upon wetting of the polymer in a body fluid, and Bosch teaches that a oxidizing agent, sodium hypochlorite is used in the treatment of warts. Thus, one of ordinary skill in the art at the time of invention would have reasonably expected that by incorporating the oxidizing agent, chlorinated isocyanurate in the silicone polymer, chlorinated isocyanurate would be slowly released by diffusion and/or hydration because it is known that chlorinated isocyanurate produces hypochlorous acid on contact with water which is a more potent germicide than sodium hypochlorite for treatment of microbial diseases. Thus, one of ordinary skill in the art at the time of invention would have reasonably expected that the crosslinked silicone polymer containing chlorinated isocyanurate would slowly release

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chlorinated isocyanurate by diffusion or/and hydration to produce hypochlorous acid, which treats warts.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on 8 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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